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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,683	04/21/2000	Lawrence Xavier Webb, M.D.	F. 003	6497

32692 7590 02/11/2004

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EXAMINER

MANTIS MERCADER, ELENI M

ART UNIT PAPER NUMBER

3737

DATE MAILED: 02/11/2004

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/553,683

Applicant(s)

WEBB, M.D., LAWRENCE XAVIER

Examiner

Eleni Mantis Mercader

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>24 & 27</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on 12/01/2003 have been fully considered but they are not persuasive. Applicant's arguments are not reflected in the claim language.

Applicant's argument stating that the references do not teach "each radio-opaque label of the plurality of radio-opaque labels is located at one intersection of the plurality of intersections in the radio-opaque pattern to provide a plurality of labeled intersections on the surgical drape" is misplaced. See for example Figure 1 of Krupnick'035, each radio-opaque label whether a number or a letter of the plurality of radio-opaque labels such as the letters A and B are located at one intersection such as intersection (0, A) and intersection (0, B) respectively, to provide a plurality of labeled intersections, such as (0, A) or (0, B) in the radio-opaque pattern to provide a plurality of labeled intersections (such as (17, K) or (24, A)). Thereby, the limitation is met. Also, the claim language does not exclude labels at the periphery of the drape.

If applicant's intent was to claim that —each radio-opaque label consists of a unique combination of a different letter and a different number, each combination itself being located at each intersection— which is not what the Applicant claims but what seems to argue, then the question is whether there is any criticality over the alternative labeling by the numbers and letters as displayed in Figure 1 of Krupnick. It appears from the disclosure that other than uniquely identifying the intersection which is exactly what the invention of Krupnick does, there is no other criticality and hence if Applicant were to claim with specificity to reflect the arguments advanced by Applicant, still the language as stated by the Examiner, would have been rejected under 103 as obvious modification with no criticality which would have been obvious to one

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skilled in the art at the time that the invention was made as an alternative functional equivalent resulting the same end result which is unique identification of the intersections. In other words, regardless whether the labels are at the periphery of the drape or at each intersection itself, the purpose is to identify the intersection and thereby they constitute functional equivalents.

With respect to the "die-cut" argument, the claims as written do not exclude such a cut and thereby the rejection is maintained.

For at least these reasons the rejection is maintained and made final.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 30-38, 41-43, 47-49 and 53-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller'762, of record in view of Krupnick'035, also of record.

Muller'762 teach all the features of the instant invention including a drape with radio-opaque grid lines 53 which are vertical and horizontal (see col. 6, lines 18-36) which are uniquely identifiable by letters and numbers as indicated by Figure 1. Adhesive is provided on a major portion of the drape (see col. 5, lines 15-18). Muller'762 does not teach the use of imaging technology wherein a pattern is obtained corresponding to the radio-opaque labels on the surgical drape.

In the same field of endeavor, Krupnick'035 teaches the use of imaging technology wherein a pattern is obtained corresponding to the radio-opaque labels on the surgical drape (see

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Figure 4 and see col. 5, lines 5-16). Krupnick'035 also teaches a cutout through the grid lines to effectuate a biopsy (see Figure 2 and see col. 5, lines 17-31).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Muller'762 to incorporate the teachings of Krupnick'035 in order to utilize imaging to more correctly identify the area for biopsy (motivation to combine provided by Krupnick'035 in col. 5, lines 15-16, reciting that imaging technology through the radio-opaque flexible substrate expedites localization of the area of interest).

4. Claims 39-40, 44-46, 50-52 and 62-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller'762 in view of Krupnick'035 and Mosby'985, all of record.

Muller'762 in view of Krupnick'035 teach all the features of the instant invention as set forth in paragraph 3 above, except for the use of radio-opaque circles and utilization of pliable material for use on breast procedures or on body parts resembling cylindrical or conical configurations such as a finger.

Mosby'985 teaches the use of radio-opaque circles and utilization of pliable material for use on breast procedures or on body parts resembling cylindrical or conical configurations such as a finger (see col. 5, lines 7-12; col. 6, lines 38-47 and col. 7, lines 1-10).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Muller'762 in view of Krupnick'035 to incorporate the teaching of Mosby'985 when using the drape during biopsy procedures of areas such as the breast or the finger to more readily localize the area of interest for biopsy using circular radio-opaque indications.

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Allowable Subject Matter

5. Claims 28 and 29 are allowed.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on 703 308-2262. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Eleni Mantis Mercader
Primary Examiner
Art Unit 3737

EMM